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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,124	12/31/2003	Scott Umlauf	036481-0146	1736

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EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 12/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/748,124	UMLAUF, SCOTT	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-41 are pending.

Claim 17 does not further limit claim 16 because claim 16 is directed to a cytokine. The recitation of cytokine in claim 16 indicates that the claim is directed to a polypeptide and is not broader than either a cytokine (as recited in claim 18) or a polynucleotide encoding cytokine (as recited in claim 17). Claim 17 will be placed into a group directed to a method of using a polynucleotide encoding an antigen and encoding a cytokine.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, drawn to a polynucleotide comprising a first promoter derived from a gene encoding a co-stimulatory molecule and a first nucleotide sequence encoding an antigen and a nucleotide sequence encoding a cytokine, wherein the cytokine selected from the group consisting of CD40L, TRANCE, and flt-3L, classifiable in class 435, subclass 320.1.

II. Claims 14, 15, 17, 20, 21, 22, 24, and 25, drawn to methods of eliciting an immune response via the polynucleotide and cytokine, a vaccine composition comprising (a) an expression vector comprising a polynucleotide encoding at least one antigen; and (b) a polynucleotide encoding at least one cytokine selected from the group consisting of CD40 ligand (CD40L), tumor-necrosis factor-related activation-induced cytokine (TRANCE), and Flt3 ligand (flt-3L), classifiable in class 514, subclass 44.

III. Claims 14, 16, 18, 19, 20, 23, 24, 25, 26, 29, 32, and 35-37, drawn to methods of eliciting an immune response via the polynucleotide and cytokine, a vaccine composition comprising (a) an expression vector comprising a polynucleotide encoding at least one antigen; and (b) at least one cytokine selected from the group consisting of CD40L, TRANCE, and flt-3L, classifiable in class 424, subclass 184.1 and class 514, subclass 2 and subclass 44.

IV. Claims 27, 30, 33, and 38-39, drawn to a vaccine composition comprising (a) at least one peptide antigen; and (b) an expression vector comprising a polynucleotide encoding at least one cytokine selected from the group consisting of CD40L, TRANCE, and flt-3L and a method of using the vaccine, classifiable in class 514, subclass 2, subclass 44, class 424, subclass 184.1.

V. Claims 28, 31, 34, 40 and 41, drawn to a vaccine composition comprising (a) at least one peptide antigen; and (b) at least one cytokine selected from the group consisting of CD40L, TRANCE, and flt-3L and a method of using the vaccine, classifiable in class 424, subclass 184.1 and class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

The method of Inventions II-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant specification does not disclose that these methods would be used together. The method of eliciting an immune response using a nucleotide encoding an antigen and a nucleotide encoding a cytokine (group II); the method of eliciting an immune response using a cytokine and a

nucleotide encoding an antigen (group III); the method of eliciting an immune response using a peptide antigen and a vector encoding a cytokine (group IV); and the method of eliciting an immune response using a peptide antigen and a cytokine (group V) are unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Each invention does not require the material that is required in the other inventions. Therefore, each method is divergent in material and steps. For these reasons the inventions II-V are patentably independent.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups II, III, IV, and V have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups II, III, IV, and V together.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of group I can be used make recombinant proteins as opposed to its use in eliciting an immune response in a vertebrate subject.

Searching the inventions of Groups I and II together would impose serious search burden. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polynucleotides and the method of eliciting an immune response are not coextensive. Prior art which teaches a polynucleotide

would not necessarily be applicable to the method of using the polynucleotide. Moreover, even if the polynucleotide product were known, the method of eliciting an immune response using the polynucleotide may be novel and unobvious in view of the preamble or active steps.

Invention I and the method in Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that the methods in Groups III and IV would be used together. The nucleotide encoding an antigen and a nucleotide encoding a cytokine (group I); the method of eliciting an immune response using a cytokine and a nucleotide encoding an antigen (group III); and the method of eliciting an immune response using a peptide antigen and a vector encoding a cytokine (group IV) are unrelated as they comprise distinct steps and utilize different products which demonstrates that each invention has a different mode of operation and different function. Each invention performs this function using a structurally and functionally divergent material. Each invention does not require the material that is required in the other inventions. Therefore, each method is divergent in material and steps. For these reasons the inventions I, III, and IV are patentably independent.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups I, III, and IV have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups I, III, and IV together.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. In the instant case the different inventions are unrelated because the method in Group V does not require the product set forth in Group I.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups I and V have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups I and V together.

Because these inventions are distinct for the reasons given above and the search required for each Group listed above is not required for any other Group listed above and the search for each group is not co-extensive, restriction for examination purposes as indicated is proper.

It would be unduly burdensome for the examiner to search and consider patentability of all of the presently pending claims, a restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

If applicant elects group I, applicants are required to elect a species from the following:

This application contains claims directed to the following patentably distinct species of the claimed invention: a cytokine selected from the group consisting of CD40L, TRANCE, and Flt-3L.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-4, 6, 7, and 9-11 are generic.

If applicant elects group II, applicants are required to elect a species from the following:

This application contains claims directed to the following patentably distinct species of the claimed invention: a cytokine selected from the group consisting of CD40L, TRANCE, and Flt-3L.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 14, 15, 17, 20, 21, 22, 24, and 25 are generic.

If applicant elects group III, applicants are required to elect a species from the following:

This application contains claims directed to the following patentably distinct species of the claimed invention: a cytokine selected from the group consisting of CD40L, TRANCE, and Flt-3L.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 14, 15, 18, 20, 21, 23, 24, 25, and 26 are generic.

If applicant elects group IV, applicants are required to elect a species from the following:

This application contains claims directed to the following patentably distinct species of the claimed invention: a cytokine selected from the group consisting of CD40L, TRANCE, and Flt-3L.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic because the generic claim lists the species.

If applicant elects group V, applicants are required to elect a species from the following:

This application contains claims directed to the following patentably distinct species of the claimed invention: a cytokine selected from the group consisting of CD40L, TRANCE, and Flt-3L.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic because the generic claim lists the species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE - Art Unit 1635, can be reached at (571) 272-0811.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman
1635